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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/966,940	11/10/97	TAMARKIN	01994-0024

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EXAMINER
DELACROIX MUIRHEI, C

ART UNIT	PAPER NUMBER
1614	17

DATE MAILED: 09/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/966,940

Applicant(s)

TAMARKIN et al.

Examiner
Cybillie Delacroix-Muirheid

Group Art Unit
1614



☒ Responsive to communication(s) filed on Mar. 2, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2-10, 15-26, 28-31, 33, and 34 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2-10, 15-26, 28-31, 33, and 34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 16

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The following is responsive to Applicant's amendment received March 2, 2000.

Claims 1, 11-14, 27 and 32 are cancelled. New claims 33-34 are added.

Claims 2-10, 15-26, 28-31 and 33-34 are currently pending.

Response to Amendment

All previous claim rejections maintained and set forth in the office action mailed Oct. 26, 1999 are **withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, a new ground of rejection is submitted hereinbelow.

Information Disclosure Statement

Applicant's Information Disclosure Statement received Aug. 7, 2000 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

New Ground of Rejection

Claim Objections

1. Claim 30 is objected to because of the following informalities: claim 30 is dependent upon cancelled claim 11. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9421288 ('288).

WO '288 discloses the invention substantially as claimed. Specifically, WO '288 discloses compositions and vaccines comprising colloidal metal, such as gold-chloride or silver, in combination with a biologically active factor such as TNF- α or a combination of biologically active factors. Said compositions/vaccines further include pharmaceutically acceptable carriers and Freund's complete adjuvant, respectively. Additionally, said compositions may be used to treat individuals suffering from cancer or immune related diseases. The vaccines may be also be administered to a mammal to vaccinate said mammal against a normally toxic biologically-active factor. Preferred routes of administration are intramuscular and intravenous and the compositions may be administered singly or in multiple doses. Please refer to the abstract; pages 1-10 and claims 1-22.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[®] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 2-10, 15-26 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9421288 ('288), supra.

WO '288 as applied above.

WO '288 does not; however, specifically disclose compositions comprising the biologically active factor TNF-alpha and a "target molecule"; however, upon further review of the instant application, it is clear that the "target molecule" is just another biologically active factor that

has a targeting function. Therefore, the additional target molecule, i.e. biologically active factor, in the claims of the instant application is obvious in view of the disclosure of WO '288, particularly the abstract, wherein it is stated that more than one biologically active factor may be used in the composition. Absent evidence to the contrary, the compositions of WO '288 containing one or more biologically active factors would encompass and render obvious the compositions of the instant invention. Furthermore, modification of the compositions of WO '288 to comprise various combinations of biologically active factors would have been motivated by the reasoned expectation of producing compositions that would be effective in treating cancer or immune diseases.

With respect to claims 8 and 21, targeted delivery of the compositions to a desired tissue is obvious in view of the WO '288, which discloses substantially similar compositions and methods.

Conclusion

Claims 2-10, 15-26, 28-31, 33-34 are rejected.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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SIX MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

Sep. 10, 2000


DWAYNE C. JONES
PRIMARY EXAMINER